

## **REMARKS**

Reconsideration and withdrawal of the objections to and rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance. The Examiner is thanked for considering claims 35-40 and 53 to be allowable.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1, 3-10 and 12-55 are now pending. Claims 1 and 10 were amended and claims 2 and 11 were cancelled, without prejudice.

No new matter is added by this amendment.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Support for the amended recitations in claims 1 and 10 is found in cancelled claims 2 and 11, respectively.

### **II. OBJECTIONS TO THE DRAWINGS**

The drawings were objected to because Figures 4a and 4b were allegedly identical. A replacement Figure 4a is submitted herewith which removes the arrow beside element 494, thereby obviating the objection.

Consequently, reconsideration and withdrawal of the objections to the drawings are respectfully requested.

### **III. 35 U.S.C. § 102 REJECTIONS**

Claims 1, 4-6, 10 and 13-16 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,117,394 (the “ ‘394 patent”). The rejection is traversed.

The amendments to claims 1 and 10 to recite that the piercing tip is retractable within the hollow chamber renders the rejection moot. More specifically, as the ‘394 patent fails to disclose and enable each and every element of the claimed invention, the rejection is obviated.

Consequently, reconsideration and withdrawal of the Section 102(b) and (e) rejections are believed to be in order and such actions are respectfully requested.

### **IV. 35 U.S.C. § 103 REJECTIONS**

Claims 2 and 11 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the ‘394 patent in view of U.S. Patent No. 6,274,087 to Preston et al. (the “ ‘087 patent”); and claims 3, 7-9, 12 and 17-19 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the ‘394 patent. The rejections will be collectively addressed and are respectfully traversed.

The instant invention is directed to, *inter alia*, a device for removing an aliquot of biological sample from a sealed receptacle comprising said sample, comprising a hollow chamber of predefined volume having inner and outer walls and top and bottom ends; a hollow piercing tip having sharp and blunt ends, wherein the blunt end is engaged to the bottom end of the hollow chamber; and a filter barrier engaged to the inner walls of the hollow chamber, wherein said piercing tip is retractable within said hollow chamber. The ‘394 patent, either alone or in combination with the ‘087 patent, fails to teach, suggest or motivate a skilled artisan to practice such an invention.

The Federal Circuit is quite clear that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, “obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Against this background, the Section 103 rejections are defective. None of the cited documents, for example, teach or suggest a device for removing an aliquot of biological sample from a sealed receptacle having a piercing tip that is retractable within a hollow chamber. Indeed, there is no motivating recitation in either the ‘394 or the ‘087 patent that would lead a skilled artisan to combine these documents.

The ‘394 patent relates to disposable tips for pipette devices. Nowhere in the patent is there any teaching or suggestion of a retractable piercing tip. Indeed, there is no embodiment in the ‘394 patent that would accommodate either a retractable piercing tip or a mechanism that would provide for a piercing tip to retract within a hollow chamber. The Examiner cannot create an embodiment not contemplated by the inventors of the ‘394 patent. Indeed, it is impermissible to add an element in the device of the ‘394 patent, i.e., a retractable piercing tip, when there is no motivation in the ‘394 patent to do so.

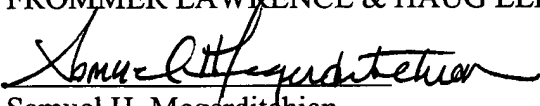
The '087 patent does not remedy this deficiency. The '087 patent relates to a diagnostic medical system, more specifically a blood cell analyzer. The '807 cites to a complex assembly having a biasing means for engaging the needle and retracting it away. (Col. 4, lines 55-59). There is no motivation in the '087 patent, however, to combine such a complex set of equipment to a simplistic pipette tip disclosed in the '394 patent. Again, there is no embodiment in the '394 patent that could accommodate the mechanisms recited in the '087 patent. Clearly, the Office Action is picking and choosing portions of two disparate references in order to formulate an obviousness rejection. This it cannot do.

Further, the Examiner is respectfully reminded that "obvious to try" is not the standard by which an obviousness rejection should be based. And as "obvious to try" would be the only standard that would give the instant Section 103 rejections any credence, the rejections must fail as a matter of law.

Consequently, reconsideration and withdrawal of the Section 103 rejections are respectfully requested.

### CONCLUSION

By this Amendment, all the claims in this application should be allowed; and this application is in condition for allowance. Favorable reconsideration of the application, withdrawal of the rejections and objections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,  
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REPLACEMENT SHEET

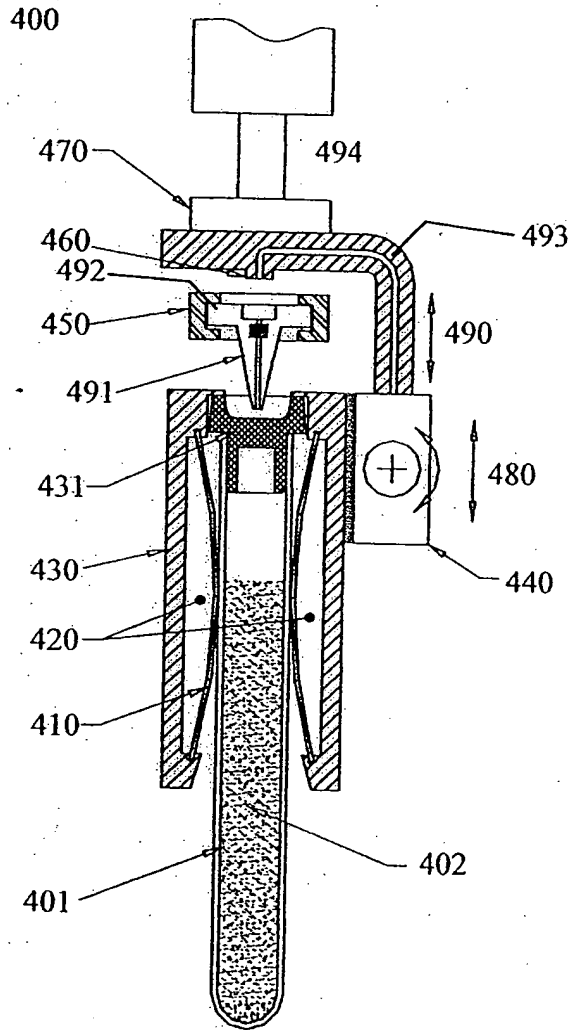


FIG. 4a